

# NCI's Clinical Trials Cooperative Groups National Meetings Report

## Summer 2009

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AACR, ASCO, ASCO GI Cancers Symposium, ASCO GU Cancers Symposium, International Symposium on Childhood, Adolescent & Young Adult Non-Hodgkin's Lymphoma, SGO, The Society for Clinical Trials, The Society of Surgical Oncology

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*The Clinical Trials Cooperative Group Program, sponsored by the National Cancer Institute (NCI), is designed to promote and support clinical trials of new cancer treatments, cancer control and prevention strategies, quality-of-life issues during and after interventions, as well as cancer imaging trials that target therapy, surveillance, and biomarkers of therapeutic responses. An issue of this report will be distributed biannually in July (post AMI, AACR, ACRIN, ASCO and SNM) and in January (post ASCO Breast Symposium, ASH, ASTRO, ISOQOL, RSNA, SABCS, SGO and AMI/SMI joint meeting) to highlight the research presentations of the Cooperative Groups and the supporting activities of NCI investigators from the Division of Cancer Treatment and Diagnosis - Cancer Therapy Evaluation Program, Cancer Diagnosis Program, Cancer Imaging Program and Radiation Research Program, and from the Division of Cancer Prevention.*

### Research Highlights in this Issue:

**ANBL0032:** This phase 3 study evaluated the addition of the anti-GD2 monoclonal antibody ch14.18 plus cytokines (GM-CSF and IL2) to standard therapy of 13-cis-retinoic acid (RA) for children with high-risk neuroblastoma following intensive induction and consolidation therapy. The ANBL0032 study demonstrated that ch14.18 plus cytokines significantly improved event-free survival for high-risk neuroblastoma patients, thereby establishing a new standard of care for this patient population after completion of intensive conduction and consolidation therapy.

**NSABP-C-08:** This is the first phase 3 adjuvant trial evaluating an anti-angiogenesis agent in combination with standard chemotherapy for patients with early stage, resectable colon cancer (stage II and stage III). Although bevacizumab in combination with chemotherapy is considered a standard, first-line treatment for patients with metastatic colorectal cancer based on improvements in overall survival demonstrated in randomized, phase 3 trials in that clinical setting, bevacizumab did not improve 3-year disease-free survival in patients with early stage disease.



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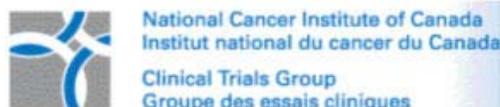
NSABP<sup>®</sup>  
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Southwest Oncology Group  
A National Clinical Research Group



## Cooperative Group Abstracts

### Breast Cancer

#### ACOSOG

Wilke LG, McCall LM, Leitch AM, Ballman KV, Hunt KK, Giuliano AE: Adherence to the National Quality Forum (NQF) Measures in a Multi-Institutional Breast Cancer Clinical Trial. The Society of Surgical Oncology, Phoenix, Arizona, Mar, 2009. Abst. P72.

[http://sso2009.abstractcentral.com/viewer?TAG\\_ACTION=VIEW\\_PROOF&ABSTRACT\\_ID=546871&SHOW\\_COMMENT=FALSE&NEXT\\_PAGE=PROOF\\_POP&SHOW\\_RECEIPT=FALSE&BLIND\\_OVERRIDE=TRUE&VIEWER\\_SHOW\\_PRINT=Y](http://sso2009.abstractcentral.com/viewer?TAG_ACTION=VIEW_PROOF&ABSTRACT_ID=546871&SHOW_COMMENT=FALSE&NEXT_PAGE=PROOF_POP&SHOW_RECEIPT=FALSE&BLIND_OVERRIDE=TRUE&VIEWER_SHOW_PRINT=Y)

Protocol(s): ACOSOG-Z0010

#### ACRIN

Hylton N, Blume J, Gatsonis C, Gomez R, Bernreuter W, Pisano E, Rosen M, Marques H, Esserman L, Schnall M: MRI tumor volume for predicting response to neoadjuvant chemotherapy in locally advanced breast cancer: Findings from ACRIN 6657/CALGB 150007. J Clin Oncol 2009; 27(15S):Abst. 529.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/529>

Protocol(s): ACRIN-6657

#### CALGB

DeMichele A, Dunn L, Gimotty P, Livasy C, Perou C, Carey L, Esserman L: Loss of p27 expression and response to neoadjuvant chemotherapy: Results from the I-SPY Trial (CALGB150007/150012, ACRIN6657). J Clin Oncol 2009; 27(15S):Abst. 11091.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/11091>

Protocol(s): CALGB-150007

Esserman LJ, Perou C, Cheang M, DeMichele A, Carey L, van 't Veer LJ, Gray J, Petricoin E, Conway K, Hylton N, Berry D: Breast cancer molecular profiles and tumor response of neoadjuvant doxorubicin and paclitaxel: The I-SPY TRIAL (CALGB 150007/150012, ACRIN 6657). J Clin Oncol 2009; 27(15S):Abst. LBA515.

<http://meeting.ascopubs.org/cgi/content/abstract/27/18S/LBA515>

Protocol(s): CALGB-150007

Lin C, Moore D, DeMichele A, Ollila D, Montgomery L, Liu M, Krontiras H, Gomez R, Esserman L: Detection of locally advanced breast cancer in the I-SPY TRIAL (CALGB 150007/150012, ACRIN 6657) in the interval between routine screening. J Clin Oncol 2009; 27(15S):Abst. 1503.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/1503>

Protocol(s): CALGB-150007

Liotta L, Pierobon M, Wulfkuhle J, Laird J, Livasy C, Espina V, Esserman L, Petricoin E: Semi-quantitative protein analysis of HER2 and ER levels in human breast cancer reveals broad expression ranges within HER2+ and ER+ phenotypes. J Clin Oncol 2009; 27(15S):Abst. 11014.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/11014>

Protocol(s): CALGB-150007

Mandelblatt J, Sheppard V, Hurria A, Kimmick G, Isaacs C, Taylor K, Luta G, Noone A, Kornblith A, Barry W: Patient preference as a determinant of breast cancer adjuvant chemotherapy use in older women: CALGB #369901. J Clin Oncol 2009; 27(15S):Abst. 9544.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/9544>

Protocol(s): CALGB-369901

van 't Veer LJ, Esserman LJ, Linn S, Rutgers E, Knauer M, Retel V, Davis SE, Lin C: Evaluation of the effect of screening on the detection of good and poor prognosis breast cancers. J Clin Oncol 2009; 27(15S):Abst. 1525.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/1525>

Protocol(s): CALGB-150007

Wulfkuhle J, Pierobon M, Laird J, Espina V, Liotta IL, Esserman L, Petricoin E: Discovery of a new phospho-HER2+/FISH- molecular subtype of human breast cancer by functional pathway mapping. J Clin Oncol 2009; 27(15S):Abst. 11009.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/11009>

Protocol(s): CALGB-150007

## ECOG

Carlson RW, O'Neill A, Vidaurre T, Gomez Moreno HL, Badve SS, Sledge GW: Randomized phase II trial of gefitinib plus anastrozole or fulvestrant in postmenopausal, metastatic breast cancer. J Clin Oncol 2009; 27(15S):Abst. 1013.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/1013>

Protocol(s): E4101

Sparano JA, Goldstein LJ, Childs BH, Shak S, Badve SS, Baehner FL, Davidson NE, Sledge GW, Gray RJ: Genotypic characterization of phenotypically defined triple-negative breast cancer. J Clin Oncol 2009; 27(15S):Abst. 500.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/500>

Protocol(s): E2197

## NCCTG

Apsy H, Roy V, Pockaj B, Northfelt D, Sticca R, Nikceovich DA, Mattar B, Fitch T, Perez EA: Surgical practice patterns following NCCTG N0338 "Phase II trial of docetaxel and carboplatin administered every two weeks as induction therapy for stage II and stage III breast cancer". J Clin Oncol 2009; 27(15S):Abst. 623.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/623>

Protocol(s): N0338

Moreno-Aspitia A, Hillman DW, Dueck AC, Carney WP, Lingle WL, Tenner KS, Lafky JM, Reinholz MM, Kutteh LA, Perez EA: Baseline and recurrence levels of soluble HER2 (sHER2) in early-stage HER2-neu positive breast cancer (HER2+BC) from the NCCTG adjuvant Intergroup trial N9831. J Clin Oncol 2009; 27(15S):Abst. 539.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/539>

Protocol(s): N9831

Reinholz MM, Kitzmann KA, Hobday TJ, Northfelt DW, LaPlant B, Allred JB, Dueck AC, Stella PJ, Lingle WL, Perez EA: Cytokeratin-19 (CK19) and mammaglobin (MGB1) gene expression in circulating tumor cells (CTCs) from metastatic breast cancer patients enrolled in the NCCTG trials, N0436 and N0437. *J Clin Oncol* 2009; 27(15S):Abst. 11095.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/11095>

Protocol(s): N0437, N0436

Sukov WR, Miller DV, Dueck AC, Tenner KS, Jenkins RB, Kaufman PA, Davidson NE, Dakhil SR, Martino S, Roy V, Perez EA: Benefit of adjuvant trastuzumab in breast cancer patients with focal HER2 amplified clones: Data from N9831 Intergroup Adjuvant Trial. *J Clin Oncol* 2009; 27(15S):Abst. 520.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/520>

Protocol(s): N9831

Tan W, Allred J, Salim M, Flynn P, Kugler JW, Stella PJ, Wiesenfeld M, Bernath AM, Fitch TR, Perez EA: N0337: Phase II study of capecitabine in combination with vinorelbine and trastuzumab for the first or second treatment of HER2+ metastatic breast cancer. *J Clin Oncol* 2009; 27(15S):Abst. 1020.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/1020>

Protocol(s): N0337

## NSABP

Yang SX, Costantino JP, Nguyen D, Jeong J, Mamounas EP, Wolmark N, Kim C, Kidwell K, Paik S, Swain SM: Correlation of levels of Akt phosphorylation at Ser473 with benefit from paclitaxel chemotherapy in NSABP B-28 patients with node-positive breast cancer. *J Clin Oncol* 2009; 27(15S):Abst. 537.

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Protocol(s): NSABP-B-28

## CNS Cancer

### CALGB

Khalil M, Wulfschuhle J, Fillmore H, Deng J, Liotta L, Petricoin E, Watson J, Broaddus W: Functional pathway mapping of human glioblastoma multiforme and brain metastases for patient tailored therapy. *J Clin Oncol* 2009; 27(15S):Abst. 2076.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/2076>

Protocol(s): CALGB-150007

### RTOG

Aldape K, Jones G, Wang M, Hegi M, Janzer R, Stupp R, Mehta M, Gilbert M: MGMT methylation testing in RTOG 0525: A phase III trial of newly diagnosed glioblastoma. *J Clin Oncol* 2009; 27(15S):Abst. 2051.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/2051>

Protocol(s): RTOG-0525

Gilbert M, Wang M, Aldape K, Sorensen A, Walker E, Regine W, Glass J, Lassman A, Mehta M: RTOG 0625: A phase II study of bevacizumab with irinotecan in recurrent glioblastoma (GBM). J Clin Oncol 2009; 27(15S):Abst. 2011.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/2011>

Protocol(s): RTOG-0625

Wang M, Cairncross G, Shaw E, Jenkins R, Scheithauer B, Brachman D, Buckner J, Souhami L, Laperriere N, Mehta M, Curran W: Cognition and quality of life after chemotherapy plus radiotherapy (RT) vs. RT for pure and mixed anaplastic oligodendrogliomas: Radiation therapy oncology group trial 9402. J Clin Oncol 2009; 27(15S):Abst. e20519.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/e20519>

Protocol(s): INT-0149

## SWOG

Swinnen LJ, Rankin C, Rushing EJ, Laura HF, Damek DM, Barger GR: Phase II study of hydroxyurea for unresectable meningioma (Southwest Oncology Group S9811). J Clin Oncol 2009; 27(15S):Abst. 2063.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/2063>

Protocol(s): S9811

## Gastrointestinal Cancer

### ACRIN

Siewert B, Gareen I, Vanness D, Herman B, Johnson CD, Gatsonis C: ACRIN 6664: Patient acceptance and preference of CT colonography compared to optical colonoscopy for colon cancer screening. J Clin Oncol 2009; 27(15S):Abst. 4034.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4034>

Protocol(s): ACRIN-6664

### CALGB

Bertagnolli MM, Niedzwiecki D, Hall M, Jewell SD, Mayer RJ, Goldberg RM, Colacchio TA, Warren RS, Redston M: Presence of 18q loss of heterozygosity (LOH) and disease-free and overall survival in stage II colon cancer: CALGB Protocol 9581. J Clin Oncol 2009; 27(15S):Abst. 4012.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4012>

Protocol(s): CR-95-036

Fuchs C, Ogino S, Meyerhardt JA, Irahara N, Niedzwiecki D, Hollis D, Saltz LB, Mayer RJ, Bertagnolli MM: KRAS mutation, cancer recurrence, and patient survival in stage III colon cancer: Findings from CALGB 89803. J Clin Oncol 2009; 27(15S):Abst. 4037.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4037>

Protocol(s): C89803

Innocenti F, Owzar K, Cox N, Evans P, Kubo M, Hollis D, Mushiroda T, Kindler HL, Nakamura Y, Ratain MJ: Heritable interleukin-17F (IL17F) gene variation and overall survival (OS) in pancreatic cancer patients (pts): Results from a genome-wide association study (GWAS) in CALGB 80303. J Clin Oncol 2009; 27(15S):Abst. 4531.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4531>

Protocol(s): CALGB-80303

Meyerhardt JA, Jackson McCleary N, Niedzwiecki D, Hollis D, Venook A, Mayer R, Goldberg R: Impact of age and comorbidities on treatment effect, tolerance, and toxicity in metastatic colorectal cancer (mCRC) patients treated on CALGB 80203. J Clin Oncol 2009; 27(15S):Abst. 4038.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4038>

Protocol(s): CALGB-80203

Meyers MO, Hollis DR, Mayer RJ, Goldberg RM, Benson III AB, Cummings B, Gunderson LL, Martenson JA, Macdonald JS, O'Connell M, Tepper JE: Use of the ratio of metastatic to examined lymph nodes to predict local recurrence in rectal cancer: Analysis of data from intergroup trial 0114. ASCO Gastrointestinal Cancers Symposium, San Francisco, California, Jan, 2009. Abst. 384.

[http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst\\_detail\\_view&confID=63&abstractID=10558](http://www.asco.org/ASCOv2/Meetings/Abstracts?&vmview=abst_detail_view&confID=63&abstractID=10558)

Protocol(s): INT-0114

## ECOG

Luketich JD, Pennathur A, Catalano P, Swanson S, DeHoyos A, Maddaus M, Nguyen N, Jobe B, Benson AB, Fernando HC: Results of a phase II multicenter study of minimally invasive esophagectomy (Eastern Cooperative Oncology Group Study E2202). J Clin Oncol 2009; 27(15S):Abst. 4516.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4516>

Protocol(s): E2202

Yoon HH, Powell M, Gibson MK, Montgomery EA, Michael H, Catalano P, Liu G, Skaar T, Dolan E, Wu X, Forastiere AA, Benson AB, Kleinberg LR, Murphy K: Outcome prediction based on genetic polymorphisms (GPs) in epidermal growth factor (EGF) pathway in patients (pts) with esophageal adenocarcinoma (EAC) treated with preoperative (preop) cisplatin (C)-based chemoradiation (CRT): Results from the Eastern Cooperative Oncology Group (ECOG). American Association of Cancer Research (AACR), Denver, Colorado, Apr, 2009. Abst. 1621.

<http://www.abstractsonline.com/viewer/viewAbstractPrintFriendly.asp?CKey={D48677CC-C7C2-4AD7-91A8-519359E5BF50}&SKey={5D0D0FA6-C791-4603-AF48-17763BE631AF}&MKey={D007B270-E8F6-492D-803B-7582CE7A0988}&AKey={728BCE9C-121B-46B9-A8EE-DC51FDFC6C15}>

Protocol(s): E1201

Yoon HH, Powell M, Murphy K, Montgomery EA, Hafez MJ, Liu G, Forastiere AA, Benson AB, Kleinberg LR, Gibson MK: Outcome prediction based on single nucleotide polymorphisms (SNPs) in DNA repair paths in patients (pts) with esophageal adenocarcinoma (EAC) treated with preoperative (preop) cisplatin (C)-based chemoradiation (CRT): Results from the Eastern Cooperative Oncology Group (ECOG). J Clin Oncol 2009; 27(15S):Abst. 4530.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4530>

Protocol(s): E1201

## NCCTG

Bardia A, Loprinzi C, Grothey A, Nelson G, Alberts S, Patiyil S, Thome S, Gill S, Sargent D: Adjuvant chemotherapy for resected stage II and III colon cancer: Comparison of widely used two prognostic calculators. J Clin Oncol 2009; 27(15S):Abst. e15031.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/e15031>

Protocol(s): Multiple Trials

Burzykowski T, Bang Y: Disease-free survival as a surrogate endpoint for overall survival in an adjuvant trial of curatively resected stomach cancer using individual patient data meta-analysis. J Clin Oncol 2009; 27(15S):Abst. 4517.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4517>

Protocol(s): Multiple Trials

Buyse ME, Pignon J: Meta-analyses of randomized trials assessing the interest of postoperative adjuvant chemotherapy and prognostic factors in gastric cancer. J Clin Oncol 2009; 27(15S):Abst. 4539.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4539>

Protocol(s): Multiple Trials

French AJ, Sinicrope F, Foster NR, Thibodeau SN, Sargent DJ, O'Connell MJ: Model-based prediction of defective DNA mismatch repair using clinicopathological variables in stage II and III colon cancers. J Clin Oncol 2009; 27(15S):Abst. 11093.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/11093>

Protocol(s): Multiple Trials

Gill S, Loprinzi C, Kennecke H, Grothey A, Nelson G, Woods R, Speers C, Alberts S, Bardia A, Sargent D: Analysis of prognostic (prog) Web-based models for stage II and III colon cancer (CC): A population-based validation of Numeracy (NUM) and ADJUVANT! Online (ADJ!). J Clin Oncol 2009; 27(15S):Abst. 4044.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4044>

Protocol(s): Multiple Trials

Jackson McCleary NA, Meyerhardt J, Green E, Yothers G, de Gramont A, Van Cutsem E, O'Connell M, Twelves C, Saltz L, Sargent D: Impact of older age on the efficacy of newer adjuvant therapies in >12,500 patients (pts) with stage II/III colon cancer: Findings from the ACCENT Database. J Clin Oncol 2009; 27(15S):Abst. 4010.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4010>

Protocol(s): Multiple Trials

Pozzo C, Ohashi Y: Meta-analyses of randomized trials assessing the influence of chemotherapy and prognostic factor in advanced/recurrent gastric cancer. J Clin Oncol 2009; 27(15S):Abst. 4550.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4550>

Protocol(s): Multiple Trials

Sinicrope F, Foster NR, Sargent DJ, Alberts SR, O'Connell MJ: Prognostic impact of body mass index upon cancer recurrence and survival in stage III colon cancer patients from adjuvant chemotherapy trials. J Clin Oncol 2009; 27(15S):Abst. 11088.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/11088>

Protocol(s): Multiple Trials

Tsikitis VL, Malireddy K, Green EA, Christensen B, Whelan R, Hyder J, Lauter D, Marcello P, Larach S, Sargent D, Nelson H: Postoperative surveillance recommendations for early-stage colon cancer based on results from the clinical outcomes of surgical therapy trial. *J Clin Oncol* 2009; 27(15S):Abst. 4013.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4013>

Protocol(s): NCCTG-93-46-51

## NSABP

Jackson-McCleary NA, Meyerhardt J, Green E, Yothers G, de Gramont A, Van Cutsem E, O'Connell M, Twelves C, Saltz L, Sargent D: Impact of older age on the efficacy of newer adjuvant therapies in >12,500 patients (pts) with stage II/III colon cancer: Findings from the ACCENT Database. *J Clin Oncol* 2009; 27(15S):Abst. 4010.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4010>

Protocol(s): NSABP-C-07

Kerr D, Gray R, Quirke P, Watson D, Yothers G, Lavery IC, Lee M, O'Connell MJ, Wolmark N, Shak S: A quantitative multigene RT-PCR assay for prediction of recurrence in stage II colon cancer: Selection of the genes in four large studies and results of the independent, prospectively designed QUASAR validation study. *J Clin Oncol* 2009; 27(15S):Abst. 4000.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4000>

Protocol(s): NSABP-C-01, NSABP-C-02, NSABP-C-04, NSABP-C-06

Kunitake H, Zheng P, Yothers G, Land SR, Fehrenbacher L, Giguere JK, Wickerham DL, Ganz PA, Ko CY: Routine preventive care and cancer surveillance in long-term survivors (LTS) of colorectal cancer: Results from NSABP Protocol LTS-01. *J Clin Oncol* 2009; 27(15S):Abst. 6500.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/6500>

Protocol(s): NSABP-LTS-01

Sargent DJ, Yothers G, Van Cutsem E, Cassidy J, Saltz L, Wolmark N, Shi Q, Buyse M, de Gramont A: Use of two-year disease-free survival (DFS) as a primary endpoint in stage III adjuvant colon cancer trials with fluoropyrimidines with or without oxaliplatin or irinotecan: New data from 12,676 patients from MOSAIC, X-ACT, PETACC-3, NSAPB C-06 and C-07, and C89803. *J Clin Oncol* 2009; 27(15S):Abst. 4011.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4011>

Protocol(s): NSABP-C-06, NSABP-C-07, C89803

Wilkinson NW, Yothers G, Lopa SH, Costantino J, Petrelli N, Wolmark N: Long-term results of surgery alone versus surgery plus 5-fluorouracil and leucovorin for stage II and stage III colon cancer: Pooled analysis of NSABP adjuvant trials C-01 through C-05. The Society of Surgical Oncology, Phoenix, Arizona, Mar, 2009. Abst. P11.

Protocol(s): NSABP-C-01, NSABP-C-02, NSABP-C-03, NSABP-C-04, NSABP-C-05

Wolmark N, Yothers G, O'Connell MJ, Sharif S, Atkins JN, Seay TE, Fehrenbacher L, O'Reilly S, Allegra CJ: A phase III trial comparing mFOLFOX6 to mFOLFOX6 plus bevacizumab in stage II or III carcinoma of the colon: Results of NSABP Protocol C-08. *J Clin Oncol* 2009; 27(15S):Abst. LBA4.

<http://meeting.ascopubs.org/cgi/content/abstract/27/18S/LBA4>

Protocol(s): NSABP-C-08

## RTOG

Rink L, Skorobogatko Y, Kossenkov A, Belinsky M, Pajak T, von Mehren M, Ochs M, Eisenberg B, Godwin A: Correlation of gastrointestinal stromal tumor (GIST) gene expression signatures and response to imatinib mesylate in the Radiation Therapy Oncology Group phase II clinical trial S-0132. *J Clin Oncol* 2009; 27(15S):Abst. 10533.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/10533>

Protocol(s): RTOG-0132

Van den Abbeele A, Gatsonis C, de Vries D, Melenevsky Y, Szot Barnes A, Yap J, Godwin A, Blevins M, Eisenberg B, Siegel B: ACRIN 6665/RTOG 0132 phase II trial of neoadjuvant imatinib mesylate (IM) for primary and recurrent operable malignant GIST: Imaging findings and correlation with genotype and GLUT4 expression. *J Clin Oncol* 2009; 27(15S):Abst. 10552.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/10552>

Protocol(s): RTOG-0132

Van den Abbeele AD, Gatsonis C, de Vries DJ, Melenevsky Y, Szot Barnes A, Yap JT, Godwin AK, Blevins M, Eisenberg B, Siegel BA: ACRIN 6665/RTOG 0132 phase II trial of neoadjuvant imatinib mesylate (IM) for primary and recurrent operable malignant GIST: Imaging findings and correlation with genotype and GLUT4 expression. *J Clin Oncol* 2009; 27(15S):Abst. 10552.

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Protocol(s): RTOG-0132

## SWOG

Leichman L, Goldman BH, Benedetti JK, Billingsley KG, Thomas CR, Iqbal S, Lenz H, Blanke C, Gold PJ, Corless CL: Oxaliplatin (OXP) plus protracted infusion 5-fluorouracil (PIFU) and external beam radiation (EBRT) prior to surgery (S) for potentially curable esophageal adenocarcinoma (EA): A Southwest Oncology Group (SWOG) phase II trial with molecular correlates (S0356). *J Clin Oncol* 2009; 27(15S):Abst. 4513.

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Protocol(s): S0356

Macdonald JS, Benedetti J, Smalley S, Haller D, Hundahl S, Jessup J, Ajani J, Gunderson L, Goldman B, Martenson J: Chemoradiation of resected gastric cancer: A 10-year follow-up of the phase III trial INT0116 (SWOG 9008). *J Clin Oncol* 2009; 27(15S):Abst. 4515.

<http://meeting.ascopubs.org/cgi/content/abstract/27/15S/4515>

Protocol(s): INT-0116

## Genitourinary Cancer

### CALGB

Rini BI, Halabi S, Rosenberg J, Stadler WM, Vaena DA, Atkins JN, Picus J, Czaykowski P, Dutcher J, Small EJ: Bevacizumab plus interferon-alpha versus interferon-alpha monotherapy in patients with metastatic renal cell carcinoma: Results of overall survival for CALGB 90206. *J Clin Oncol* 2009; 27(15S):Abst. LBA5019.

<http://meeting.ascopubs.org/cgi/content/abstract/27/18S/LBA5019>

Protocol(s): CALGB-90206

## ECOG

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Protocol(s): E5803

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Protocol(s): SWOG-4B951

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Protocol(s): SWOG-4B951

## RTOG

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Protocol(s): RTOG-86-10, RTOG-94-13, RTOG-92-02, RTOG-85-31

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Protocol(s): RTOG-92-02, RTOG-94-13

## SWOG

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Protocol(s): S9921

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Protocol(s): S0354

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Protocol(s): INT-0080

## Gynecologic Cancer

### GOG

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Protocol(s): GOG-0229E

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Protocol(s): Multiple Trials

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Protocol(s): GOG-0157

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Protocol(s): GOG-0172

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Protocol(s): Multiple Trials

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Protocol(s): GOG-0076DD

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Protocol(s): Multiple Trials

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Protocol(s): GOG-0114

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Protocol(s): Multiple Trials

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Protocol(s): GOG-0157

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Protocol(s): GOG-0172

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Protocol(s): GOG-0229C

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Protocol(s): GOG-0229C

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Protocol(s): GOG-0173

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Protocol(s): GOG-9911

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Protocol(s): GOG-01290

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Protocol(s): GOG-0107

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Protocol(s): GOG-0210

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Protocol(s): GOG-0175

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Protocol(s): GOG-0232B

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Protocol(s): GOG-56

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Protocol(s): GOG-9919

## *NCIC Clinical Trials Group*

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Protocol(s): NCIC-148, NCIC-160

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Knight D, Tiersten AD, Liu PY, Smith HO, Wilczynski SP, Robinson WR, Markman M, Fruehauf JP, Alberts DS: Chemotherapy resistance as a predictor of progression-free survival in ovarian cancer patients treated with neoadjuvant chemotherapy and surgical cytoreduction followed by intraperitoneal chemotherapy: A Southwest Oncology Group Study. *Western Association of Gynecologic Oncologists*, Vancouver, BC, Canada, Jun, 2009.

Protocol(s): S0009

## **Head and Neck Cancer**

### *ECOG*

Argiris A, Ghebremichael M, Gilbert J, Burtness BA, Forastiere AA: A phase III randomized, placebo-controlled trial of docetaxel (D) with or without gefitinib (G) in recurrent or metastatic (R/M) squamous cell carcinoma of the head and neck (SCCHN): A trial of the Eastern Cooperative Oncology Group (ECOG). *J Clin Oncol* 2009; 27(15S):Abst. 6011.

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Protocol(s): E1302

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Protocol(s): E3301

Gilbert J, Argiris A, Haigentz M, Lee J, Burtness BA: Phase II randomized trial of bortezomib (B) plus irinotecan (I) or B with addition of I at progression in recurrent (R) or metastatic (M) squamous cell carcinoma of the head and neck (SCCHN) (E1304): A trial of the Eastern Cooperative Oncology Group. J Clin Oncol 2009; 27(15S):Abst. 6020.

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Protocol(s): E1304

## RTOG

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Protocol(s): RTOG-0129

## Leukemia, Myelodysplasia, and Transplantation

### CALGB

Becker H, Marcucci G, Maharry K, Margeson D, Radmacher MD, Whitman SP, Mrózek K, Baer MR, Larson RA, Bloomfield CD: NPM1 mutations as an independent prognosticator for older cytogenetically normal acute myeloid leukemia (CN AML). J Clin Oncol 2009; 27(15S):Abst. 7000.

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Protocol(s): CALGB-10201, CALGB-9720, CALGB-20202

Marcucci G, Maharry K, Whitman SP, Paschka P, Baldus CD, Langer C, Mrózek K, Kolitz JE, Larson RA, Bloomfield CD: Improving the molecular risk classification for younger (<60 years) de novo cytogenetically normal acute myeloid leukemia (CN AML) patients (pts). J Clin Oncol 2009; 27(15S):Abst. 7002.

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Protocol(s): CALGB-19808, CALGB-9621, CALGB-20202

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Protocol(s): CALGB-19808, CALGB-9621, CALGB-20202

## COG

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Protocol(s): ADVL0013, ADVL0319

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Protocol(s): A2971

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Protocol(s): POG-9404, POG-8704

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Protocol(s): AALL0232

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Protocol(s): AALL05B1

Mullighan CG, Zhang J, Harvey RC, Collins-Underwood JR, Tasian SK, Schulman BA, Phillips LA, Loh M, Su X, Liu W, Devidas M, Atlas SR, Chen I, Clifford RJ, Gerhard DS, Carroll WL, Reaman GH, Smith M, Downing JR, Hunger SP, Willman CL: Frequent JAK mutations in pediatric acute lymphoblastic leukemia with poor outcome: A new therapeutic target in resistant disease. American Association of Cancer Research (AACR), Denver, Colorado, Apr, 2009. Abst. LB-92.

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Protocol(s): POG-9906

Rollins N, Winick N, Gimi B, Chia J, Wang J: Comparison of Leukemic and Controls Subjects Using Diffusion Tensor Imaging. *Pediatr Blood Cancer* 2009; 52(6):Abst. P150.

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Protocol(s): AALL06N1

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Protocol(s): P9407

Yang JJ, Yang W, Cheng C, Devidas M, Cao X, Campana D, Borowitz M, Willman CL, Bowman W, Reaman GH, Carroll WL, Hunger S, Evans WE, Pui C, Relling MV: Characterization of germline genetic variants underlying racial disparities of childhood leukemia outcome. American Association of Cancer Research (AACR) Cancer Health Disparities, Carefree, Arizona, Feb, 2009. Planery Session 3.

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Protocol(s): POG-9900, POG-9904, POG-9905, POG-9906

## ECOG

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Protocol(s): E1900

## Lymphoma and Plasma Cell Disorders

### COG

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Protocol(s): A5971

Burke MJ, Dayton V: Treatment of a CNS Relapse while on Therapy for Burkitt Lymphoma. *Hematology Meetings Reports* 2009; 3(5):Abst. 97.

Protocol(s): ANHL01P1

Coustan-Smith E, Sandlund JT, Perkins S, Chen HR, Chang M, Abromowitch M, Campana D: Minimal Disseminated Disease In Childhood T-Cell Lymphoblastic Lymphoma: A Report From The Children's Oncology Group. *Hematology Meetings Reports* 2009; 3(5):Abst. 17.

Protocol(s): A5971

Goldman SC, Lynch J, Harrison L, Cairo M: Effective and Safe Acute Tumor Lysis Syndrome (ATLS) Prophylaxis with Rasburicase and Non-Alkaline Hydration in Children and Adolescents with Advanced Stage III/IV Intermediate Risk B-Cell Non-Hodgkin Lymphoma (B-NHL): A Children's Oncology Group Report. *Pediatr Blood Cancer* 2009; 52(6):Abst. P145.

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Protocol(s): ANHL01P1

Goldman SC, Lynch J, Harrison L, Cairo M: Effective and Safe Acute Tumor Lysis Syndrome (ATLS) Prophylaxis and Treatment (P+T) with Rasburicase (R) and Non-Alkaline Hydration in Children and Adolescents (C+A) with High –Risk FAB Group C Mature B- Non-Hodgkin Lymphoma (B-NHL): A Children's Oncology Group Report. Hematology Meetings Reports 2009; 3(5):Abst. 146.  
Protocol(s): ANHL01P1

Goldman SC, Lynch J, Harrison L, VandeVen C, Gross TG, Shiramizu B, Sanger W, Perkins S, Cairo M: Safety and Kinetics of Rituximab (R) following Chemoimmunotherapy (Rituximab + FAB Chemotherapy) in Children and Adolescents with Mature B-cell Non-Hodgkin Lymphoma (B-NHL): A Children's Oncology Group Report. Hematology Meetings Reports 2009; 3(5):Abst. 138.  
Protocol(s): ANHL01P1

Goldman SC, Lynch J, Harrison L, VandeVen C, Gross TG, Shiramizu B, Sanger W, Perkins S, Cairo M: Rituximab combined with FAB Group B4 therapy in children and adolescents with stage III/IV mature BNHL : A Children's Oncology Group Report. Hematology Meetings Reports 2009; 3(5):Abst. 141.  
Protocol(s): ANHL01P1

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Protocol(s): ANHL0221

Gross TG, Orjuela MA, Hayashi RJ, Park J, Perkins S, Cairo M, Lynch J: Pediatric, Refractory Post-Transplant Lymphoproliferative Disease (PTLD) Following Solid Organ Transplantation (SOT): a Children's Oncology Group Phase II Study. Hematology Meetings Reports 2009; 3(5):Abst. 126.  
Protocol(s): ANHL0221

Kraveka JM, Weitzman S, Smith LM, Lynch J, Chang M, Kinney MC, Perkins S, Laver J, Gross TG, Weinstein H: Advanced-Stage Anaplastic Large-Cell Lymphoma in Children and Adolescents: Results of ANHL0131, a Randomized Phase III Trial with Standard APO (Doxorubicin, Prednisone, Vincristine) Versus Consolidation with a Regimen Including Vinblastine: A Report from the Children's Oncology Group. Hematology Meetings Reports 2009; 3(5):Abst. 68.  
Protocol(s): ANHL0131

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Protocol(s): A5971

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Protocol(s): A5971

## NCCTG

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Protocol(s): N0489

## SWOG

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Protocol(s): INT-0141

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Protocol(s): INT-0141

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Protocol(s): S0120

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Protocol(s): S0434

## Lung Cancer

### ACOSOG

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Protocol(s): ACOSOG-Z0030

## CALGB

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Protocol(s): CALGB-30407

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Protocol(s): CALGB-9238

Stinchcombe TE, Hodgson L, Herndon JE, Kelley MJ, Cicchetti M, Ramnath N, Niell HB, Atkins JN, Green MR, Vokes EE: Clinical factors predictive of overall survival (OS) and the identification of prognostic groups in patients (pts) with unresectable stage III non-small cell lung cancer (NSCLC) treated with chemoradiotherapy on Cancer and Leukemia and Group B trial (CALGB) 39801. *J Clin Oncol* 2009; 27(15S):Abst. 7535.

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Protocol(s): CALGB-39801

## ECOG

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Protocol(s): E3503

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Protocol(s): E4599

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Protocol(s): EST-3589

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Protocol(s): E4599

## NCCTG

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Protocol(s): Multiple Trials

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Protocol(s): N0028

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Protocol(s): Multiple Trials

## NCIC Clinical Trials Group

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Protocol(s): JBR10

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Protocol(s): JBR10

## RTOG

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Protocol(s): RTOG-0214

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Protocol(s): RTOG-0239

## SWOG

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Protocol(s): S0342, S0536

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Protocol(s): S0536

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Protocol(s): S0509

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Protocol(s): S0124

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Protocol(s): S0536, S0342

## Melanoma/Skin Cancers

### NCCTG

Markovic SN, Suman VJ, Kottschade LA, Amatruda T, McWilliams RR, Dakhil SR, Nikcevich DA, Morton RF, Fitch TR, Jaslowski AJ: A phase II trial of carboplatin (C) and nab-paclitaxel (ABI-007-nab-P) in patients with unresectable stage IV melanoma: Final data from N057E. J Clin Oncol 2009; 27(15S):Abst. 9055.

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Protocol(s): N057E

## SWOG

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Protocol(s): S0331

## Sarcoma/Bone and Soft Tissue Cancers

### COG

van Doorninck J, Ji L, Okamatsu C, Cooper A, Wing M, Womer R, Krailo M, Ladanyi M, Shimada H, Triche TJ, Sposto R, Lawlor ER: Ewing family tumors that do not over-express BMI-1 are a distinct subclass that arise from alternate mechanisms of molecular transformation. *American Association of Cancer Research (AACR), Denver, Colorado, Apr, 2009. Abst. 2185.*

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Protocol(s): AEWS0031

### RTOG

Howell D, James J, Hartsell W, Suntharalingam M, Machtay M, Suh J, Demas W, Sandler H, Kachnic L, Berk L: Randomized trial of short-course versus long-course radiotherapy for palliation of painful vertebral bone metastases: A retrospective analysis of RTOG 97–14. *J Clin Oncol* 2009; 27(15S):Abst. 9521.

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Protocol(s): RTOG-97-14

### SWOG

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Protocol(s): S0345

## Other Cancer

### COG

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Protocol(s): ANBL0421

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Protocol(s): ANBL00B1

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Protocol(s): ANBL00B1

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Protocol(s): ANBL07B1

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Protocol(s): AE22

Malempati S, Weigel B, Ingle AM, Ahern CH, Carroll JM, Roberts CT, Fox FE, Voss S, Adamson PC, Blaney SM: A phase I trial and pharmacokinetic study of IMC-A12 in pediatric patients with relapsed/refractory solid tumors: A Children's Oncology Group Phase I Consortium study. *J Clin Oncol* 2009; 27(15S):Abst. 10013.

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Protocol(s): ADVL0712

Malogolowkin MH, Krailo M, Frazier LA, Olson TA: Study of cisplatin, etoposide, bleomycin, and escalating dose cyclophosphamide therapy for children with high-risk germ cell tumors: A Children's Oncology Group report. *J Clin Oncol* 2009; 27(15S):Abst. 10035.

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Protocol(s): INT-0097

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Protocol(s): AHOD0031

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Protocol(s): ANUR0631

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Protocol(s): ANUR0631

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Protocol(s): AE22

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Protocol(s): ANUR0631

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Protocol(s): ACCL0331

Stegenga K, Docherty S, Phillips-Salimi C, Donovan M, Hendricks-Ferguson VL, Barnes YJ, Haase JE: The SMART Approach: An Innovative Method to Multi-site Qualitative Data Collection and Analysis. *Oncol Nurs Forum* 2009; 36(1):Abst. CK.

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Protocol(s): ANUR0631

Wagner LM, Perentesis JP, Reid JM, Ames MM, Safgren SL, Nelson MD, Ingle AM, Blaney SM, Adamson PC: Phase I trial and pharmacokinetic study of two schedules of vincristine, oral irinotecan, and temozolomide (VOIT) for children with refractory solid tumors: A Children's Oncology Group Phase I Consortium study. *J Clin Oncol* 2009; 27(15S):Abst. 10017.

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Protocol(s): ADVL0414

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Protocol(s): ADVL0413

Yu AL, Gilman AL, Ozkaynak MF, London WB, Kreissman S, Chen HX, Matthay KK, Cohn SL, Maris JM, Sondel P: A phase III randomized trial of the chimeric anti-GD2 antibody ch14.18 with GM-CSF and IL2 as immunotherapy following dose intensive chemotherapy for high-risk neuroblastoma: Children's Oncology Group (COG) study ANBL0032. *J Clin Oncol* 2009; 27(15S):Abst. 10067z.

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Protocol(s): ANBL0032

## ECOG

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Protocol(s): E2Z02

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Protocol(s): Multiple Trials

## NCCTG

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Protocol(s): N06CA

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Protocol(s): N04C7

Kottschade LA, Sloan JA, Mazureczak MA, Johnson DB, Murphy B, Rowland KM, Smith DA, Berg A, Stella PJ, Loprinzi CL: The use of vitamin E for prevention of chemotherapy-induced peripheral neuropathy: A phase III double-blind, placebo controlled study—N05C3. *J Clin Oncol* 2009; 27(15S):Abst. 9532.

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Protocol(s): N05C3

Liu H, Sloan JA, Sargent DJ, Satele DV, Schaefer PL, Halyard MY, Grothey A, Garces YI, Brown PD, Buckner JC: Assessing simple measures of patient-reported (PR) fatigue for oncology clinical trials: A pooled analysis of 3,915 patients. *J Clin Oncol* 2009; 27(15S):Abst. 9563.

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Protocol(s): Multiple Trials

Loprinzi CL, Qin R, Stella PJ, Rowland KM, Graham DL, Erwin N, Dakhil SR, Jurgens DJ, Burger KN: Pregabalin for hot flashes in women: NCCTG trial N07C1. *J Clin Oncol* 2009; 27(15S):Abst. 9513.

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Protocol(s): N07C1

Sloan JA, Liu H, Sargent DJ, Satele D, Schaefer PL, Halyard MY, Grothey A, Garces YI, Brown PD, Loprinzi CL, Buckner JC: A patient-level pooled analysis of the prognostic significance of baseline fatigue for overall survival (OS) among 3,915 patients participating in 43 North Central Cancer Treatment Group (NCCTG) and Mayo Clinic Cancer Center (MC) oncology clinical trials. *J Clin Oncol* 2009; 27(15S):Abst. 9599.

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Protocol(s): Multiple Trials

Tang H, Foster NR, Grothey A, Ansell SM, Sargent DJ: Excessive false-positive errors in single-arm phase II trials: A simulation-based analysis. *J Clin Oncol* 2009; 27(15S):Abst. 6512.

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Protocol(s): Multiple Trials

Wolf SL, Qin R, Barton DL, Sloan JA, Liu H, Aaronson NK, Satele DV, Green NB, Mattar BI, Loprinzi CL: Relationship of sensory symptoms and motor function in patients with chemotherapy-induced peripheral neuropathy (CIPN) utilizing the EORTC QLQ CIPN20: NCCTG study N06CA. *J Clin Oncol* 2009; 27(15S):Abst. 9587.

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Protocol(s): N06CA

## *NCIC Clinical Trials Group*

Oza AM, Kollmannsberger C, Hirte H, Welch S, Siu L, Mazurka J, Sederias J, Doyle LA, Eisenhauer E: Phase I study of temsirolimus (CCI-779), carboplatin, and paclitaxel in patients (pts) with advanced solid tumors: NCIC CTG IND 179. *J Clin Oncol* 2009; 27(15S):Abst. 3558.

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Protocol(s): NCIC-179

## *NSABP*

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Protocol(s): NSABP-B-30, NSABP-B-31, NSABP-B-32, NSABP-B-34, NSABP-B-35, NSABP-B-36, NSABP-B-38, NSABP-B-39, NSABP-C-08, NSABP-R-04

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## SWOG

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## NCI/CTEP Abstracts & Activities

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## Significant Publications of Interest

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